

247 CMR 6.00: REGISTRATION, MANAGEMENT AND OPERATION
OF A PHARMACY OR PHARMACY DEPARTMENT

6.01: Application for Registration to Manage and Operate a Pharmacy or a Pharmacy
Department; Inspection of a Proposed Pharmacy or Pharmacy Department

(2) ~~When a pharmacist applies for a registration to manage and operate a pharmacy or pharmacy department on behalf of a corporation, in addition to the requirements of 247 CMR 6.01(1), the~~ A completed application to operate a pharmacy shall include:

~~(4) No application for registration to manage and operate a pharmacy or pharmacy department shall be acted upon by the Board less than 15 days after receipt by the Board of the fully and properly completed application.~~

(5)(4) Before acting upon any application for registration to manage and operate a pharmacy or pharmacy department, the Board may require a hearing and, if requested to do so, the applicant shall personally appear before the Board to answer questions to enable the Board to determine that issuance of a permit would be in the best interests of the public health, welfare and safety as set forth in M.G.L. c. 112, § 39.

(6)(5) The Board ~~shall~~ may require an inspection of the pharmacy or pharmacy department before final approval of the application is granted. All proposed pharmacies and pharmacy departments shall comply with the following requirements:

(a) No application for registration to manage and operate a pharmacy or pharmacy department shall be approved unless, upon inspection, the following is maintained on the pharmacy premises:

1. ~~¶~~ the most recent edition of the Massachusetts List of Interchangeable Drugs (MLID), including the Orange Book, Additional List, Exception List, and the latest supplements thereto;

2. a current copy or electronic version (with quarterly updates) of one of the following: a compendia appropriate to the practice setting approved by the pharmacist manager of record.

~~a. Facts and Comparisons;~~

~~b. United States Pharmacopoeia/Dispensing information (USP/DI), Volumes I and II;~~

~~c. The American Hospital Formulary Service Drug Information; or~~

~~d. American Medical Association Drug Evaluations; or~~

3. ~~a current~~~~the most recent~~ copy of Board Regulations; 247 CMR 1.00 through 13.00 et seq.;

(d) Patient Consultation Area.

1. A pharmacy must provide a separate consultation area, designated with signage stating “Patient Consultation Area”, designed to provide adequate privacy for confidential visual and auditory patient counseling. The private consultation area must be accessible by a patient from the outside of the prescription dispensing area without having to traverse a stockroom or the prescription dispensing area.
2. This requirement shall be effective for all new or relocating pharmacies (sixty days after the rule effective date.) All existing pharmacies must comply (within two years of the rule effective date).

(7) The Board shall issue a permit indicating the pharmacy’s or pharmacy department’s registration number if the Board finds, in ~~it’s~~ its reasonable discretion, that approving the application would be consistent with the best interest of public health, welfare and safety.

6.02: Conditions for Continuing Registration and Operation of a Pharmacy or Pharmacy Department

Except as provided by exemptions set forth in 247 CMR 12.00 with respect to restricted pharmacies and 247 CMR 13.00 with respect to nuclear pharmacies, the following conditions shall apply to the continuing operation of a pharmacy or pharmacy department:

(7) A pharmacy or a pharmacy department shall conspicuously display, in legible letters not less than one inch high, over, on or adjacent to the main entrance of the pharmacy or pharmacy department, the name of the pharmacist Manager of Record who is responsible for the management and operation of the pharmacy or pharmacy department ~~and in whose name the permit has been issued by the Board.~~

6.03: Requirements for Reporting to the Board a Change in the Management, Operation and/or Ownership of a Pharmacy or Pharmacy Department

(1) Whenever there is a change in the pharmacist Manager of Record ~~management~~ of a pharmacy or pharmacy department ~~such that said pharmacy or pharmacy department is to be managed by a registered pharmacist other than the pharmacist who completed the initial application for registration to manage and operate the pharmacy or pharmacy~~

~~department~~, an application for a change in pharmacist Manager of Record shall be obtained from, and be promptly submitted to, the Board. A completed application shall:

(a) ~~B~~ be fully and properly completed and signed, under the penalties of perjury, by the ~~registered pharmacist who is to manage and operate~~ a duly authorized representative of the pharmacy or pharmacy department;

(b) have attached thereto a sworn statement confirming that a complete inventory of controlled substances in Schedules II, III, IV and V signed by the outgoing pharmacist Manager of Record and the incoming pharmacist Manager of Record has been taken and filed with the pharmacy's controlled substance records. In the event the outgoing pharmacist Manager of Record is unavailable due to death, serious illness, or termination for inappropriate handling of controlled substances, a staff pharmacist may be authorized to ~~shall~~ sign the inventory, provided the Board is notified at the time the application is submitted and submit a written statement to the Board explaining why that the staff pharmacist is signing the inventory on behalf of the outgoing pharmacist Manager of Record;

(c) ~~be accompanied by a statement of the scheduled hours during which the pharmacy or pharmacy department is to remain open, including the time of opening and closing during the regular business hours for each day of the week;~~

(d)(c) be accompanied by an application for a certificate of fitness, if applicable;

(e)(d) have attached thereto the pharmacy permit and, if applicable, the pharmacy or pharmacy department's certificate of fitness;

(f)(e) be accompanied by required fee(s) ~~check(s) or money order(s) in the appropriate amount made payable, to the "Commonwealth of Massachusetts Board of Registration in Pharmacy"~~; and

(g)(f) be accompanied by any additional information as determined by the Board.

6.04: Requirements for Reporting to the Board a Change in the Configuration, Square Footage, or Location of a Pharmacy or Pharmacy Department

(2) The following requirements shall apply to any pharmacy or pharmacy department ~~relocating within the same structure or moving to a new address location outside the structure~~. The pharmacy or pharmacy department shall:

(a) ~~S~~submit to the Board a new application and payment of the appropriate fee in accordance with the requirements of 247 CMR 6.01(1) in advance of any relocation;

~~(b) in all cases where the pharmacy's address changes, a new registration number shall be issued by the Board and return previously issued permits shall be returned with the application; and~~

(c) a pharmacy or pharmacy department which has moved to a new address location shall not begin to operate in said location until the application has been approved by the Board and until the pharmacy or pharmacy department pharmacist Manager of Record has received from the Board a permit to manage and operate the pharmacy and a controlled substances registration.

6.05: Continuing Responsibilities of All Registered Pharmacists

(1) A registered pharmacist who changes his or her ~~place of employment~~, residence, and/or name shall notify the Board of such change(s) in writing within ten working days of such change(s). In the case of a change of name, the pharmacist shall submit a sworn statement indicating that the pharmacist has changed his or her name and a photocopy of a valid picture identification card and any other documentation that may be required by the Board. ~~If the pharmacist is a requesting a name change as the result of marriage, the pharmacist shall submit a certified copy of his or her marriage certificate.~~

6.06: Renewal of a Pharmacy Permit

(2) Application for renewal of a pharmacy or pharmacy department permit shall be made by the pharmacist Manager of Record a duly authorized representative of the pharmacy on a renewal application form provided by the Board. Such renewal form shall be fully and properly completed and submitted to the Board in a timely manner.

6.07: Pharmacist Manager of Record

~~(1) It shall be the responsibility of the pharmacist Manager of Record to fully and properly complete and sign an application for an initial permit to manage and operate a pharmacy or pharmacy department, as outlined in 247 CMR 6.01.~~

~~(2) It shall be the responsibility of the pharmacist Manager of Record to fully and properly complete and sign an application for renewal of a pharmacy or pharmacy department permit, as outlined in 247 CMR 6.06.~~

(3)(1) The responsibilities of the pharmacist Manager of Record shall include, but may not be limited, to the following:

(i) taking an inventory of controlled substances in Schedules II, III, IV and V, based upon federal biennial inventory requirements, ~~which the pharmacist Manager of Record shall sign and forward to the Board upon commencement and termination of employment~~, pursuant to the requirements of 247 CMR 6.03(b); and

~~(4)~~(2) A pharmacist Manager of Record shall not be the Manager of Record of more than one pharmacy or pharmacy department at a time.

6.08: Certificate of Fitness Issued by the Board Permitting the Manufacture and Sale of Alcoholic Beverages

~~(5) No application for a certificate of fitness shall be considered by the Board until 15 days after it has been received by the Board.~~

6.09: Closing of a Pharmacy or Pharmacy Department

(2) Within ten days of the closure of a pharmacy or pharmacy department, the following shall be completed by the pharmacy or pharmacy department ~~pharmacist Manager of Record~~:

- (a) the pharmacy permit shall be returned to the Board;
- (b) the pharmacy controlled substance registration shall be returned to the Board;
- (c) the pharmacy certificate of fitness, if issued, shall be returned to the Board;
- and
- (d) the Board shall be notified that all controlled substances have been disposed of in accordance with federal regulations at 21 CFR 1307.21.

6.10: Distribution of Controlled Substances Upon Discontinuance or Transfer of Business of a Pharmacy or Pharmacy Department

(2) After proper notification, the transfer of controlled substances may occur provided the following procedures are adhered to:

- (a) On the date of the transfer, a complete inventory of all controlled substances in Schedules II through V shall be taken in accordance with federal and state law;
- (b) said inventory shall be signed by the pharmacist Manager of Record of the transferor pharmacy or pharmacy department and the pharmacist Manager of Record of the transferee pharmacy or pharmacy department. In the event the either pharmacist Manager of Record is unavailable due to death, serious illness, or termination for inappropriate handling of controlled substances, a staff pharmacist may be authorized to shall sign the inventory, provided the Board is notified at the time the application is submitted and submit a written statement to the Board explaining why the staff pharmacist is signing the inventory;

